REMARKS

Claims 14-34 are pending in this application. Claims 1-13 have been canceled. Claims 14-34 have been added. Support new claim 14 may be found on page 7, line 18 through page 8, line 6 and Example 1. Support for new claims 15 and 16 may be found in Example 1 of the specification. Support for new claim 17 may be found from the specification generally and the Examples. Support for new claims 18-23 may be found respectively, in original claims 2-7. Support for new claims 24 and 25 may be found in original claim 9. Support for new claims 26 and 27 may be found in original claim 10. Support for new claims 28-34 may be found on page 9, line 12-18 of the specification. New claims 14-34 in no way add new matter to the specification. As such, entry and consideration thereof are respectfully requested.

Rejections under 35 U.S.C. §101

Claim 13 has been rejected under 35 U.S.C. §101 as being an improper "use" claim. Claim 13 has been cancelled thus obviating this rejection.

Rejections under 35 U.S.C. §112, first paragraph

Claims 10 and 12 have been rejected under 35 U.S.C. §112, first paragraph for lack of enablement. The Examiner asserts that the specification is only enabled for treating viral or bacterial

infection using the recited mushroom extract, but not for the prevention of viral or bacterial diseases. Claims 10 and 12 have been cancelled and new claims 26-34 are drawn to methods of treating bacterial or viral diseases. As such, the rejection is overcome.

Rejections under 35 U.S.C. §112, second paragraph

Claim 13 has been rejected under 35 U.S.C. §112, second paragraph as being indefinite. More specifically, claim 13 has been rejected for being drawn to a "use" but failing to set forth any positive steps. Claim 13 has been cancelled thus obviating this rejection.

Rejections under 35 U.S.C. §102

Claims 1-13 have been rejected under 35 U.S.C. §102 as being anticipated by or obvious over Iizuka (U.S. '627), Sugano et al. (U.S. '760) or Ishida et al. (U.S. '780). Each of the references is asserted to disclose an anti-tumor pharmaceutical composition comprising an extract of *L. edodes* mycelium as the active ingredient and that the compositions also have anti-viral activity. The Examiner asserts that the extracts of the references appear to be identical to the extracts of the invention or that any differences are insignificant.

a) *U.S. '627 and U.S. '760*

The present invention, as encompassed by new claim 14, is drawn to an extract of *Lentinus edodes* mycelium, which is prepared by

crushing and delignifying a solid medium containing *Lentinus edodes* mycelia in the presence of water and one or more enzymes selected from the group consisting of cellulase, protease and glucosidase to prepare a suspension, wherein said solid medium is based on bagasse and defatted rice brand; and

raising the temperature of said suspension to inactivate the enzymes;

wherein said extract enhances γδT cell activity.

Thus, the invention of new claim 14 is drawn to an extract product, which is defined, in part, by the process used to make it. The process used to make the extract of the invention has three features.

i) the use of a solid bran medium based on bagasse and defatted rice bran;

ii) a step of crushing and delignifying a solid medium containing *Lentinus edodes* mycelia in the presence of water and one or more enzymes selected from the group consisting of cellulase, protease and glucosidase, to prepare a suspension; and

iii) a step of raising the temperature to inactivate the enzymes.

The process used to prepare the extract of claim 14 results in a unique and novel product which is distinct from the product of U.S. '627 and U.S. '760. One of the unique features of the present invention is the ability to enhance γδT cell activity.

The method used to prepare the extract of the invention differs from the method used in U.S. '760 in features i) and ii), above. The method used with the present invention results in a different product. For example, the product resulting from the extraction and preparation method of claim 14 has glucose as a primary component with a glucose content of approximately 40%.

Both U.S. '627 and U.S. '760 use the same raw material and method of preparing an extract from *Lentinus edodes*. As such, the resulting extract from both references is the same. As noted previously, the preparation of U.S. '627 and U.S. '760 lacks features i) and ii), above. The extract of U.S. '760 "was found to contain sugar and protein primarily consisting of xylose" and the samples contained respectively 39.0% (LAP-1) and 30.4% (LAP-2) xylose. Thus, the resulting product of the invention is different from the product of U.S. '760 and U.S. '627 due to the recited process of preparation.

The present extract product has the additional feature that it enhances γδT cell activity, whereas the disclosures of U.S. '760

and U.S. '627 are directed to methods of treating viral hepatitis and cancer, respectively. The ability to enhance γδT cell activity is dependent on the extraction/preparation method recited in claim 14. As such, the feature of the present invention of enhancing γδT cell activity would not be achieved with the extracts of U.S. '627 and U.S. '760. As such, the present invention is not anticipated by U.S. '760 or U.S. '627 and withdrawal of the rejections is respectfully requested.

The invention of claim 16 is further distinguished from the disclosures of U.S. '760 and U.S. '627 in the recitation of a component composition of approximately,

25.3% carbohydrates,

19.7% proteins,

2.6% polyphenols,

8% crude fat,

22% crude ash and

20% soluble nitrogen-free materials other than carbohydrates.

The sample designated as LAP-1 in U.S. '760 contains:

340 μg/mg of protein (which corresponds to 34.0%),

652 μg/mg of sugar (corresponding to 65.2%), and

8 μg/mg of "others" (corresponding to 0.8%).

The sample designated as LAP-2 in U.S. '760 contains:

168 μg/mg of protein (corresponding to 16.8%),

484 μg/mg of sugar (corresponding to 48.4%), and

348 µg/mg of "others" (corresponding to 34.8%).

Thus, the composition of the present invention of claim 16 and dependent claims thereon, is further distinguished from the compositions of U.S. '760 and U.S. '627.

b) U.S. '780

U.S. '780 discloses that the broth containing the distiller solubles is used as the culture medium for *L. edodes* mycelium and that the extract is prepared from the mycelium itself after being separated from the culture broth. Thus, the extract disclosed in U.S. '780 lacks all three features of the present invention discussed above. The resulting extract of U.S. '780 is different from the extract of the present invention and would lack the γδT cell enhancing activity associated with the present invention. As such, the present invention is not anticipated by the reference and withdrawal of the rejection is respectfully requested.

Claims 1-11 and 13 have been rejected as being anticipated by or obvious over Iizuka et al. (EP '601) or Koga et al. (U.S. '239). EP '601 and US '239 are asserted to each disclose an anti-viral composition made from an extract of *L. edodes* mycelium and the in vivo administration thereof. The Examiner asserts that the extracts of the references appear to be identical to the extracts of the invention or that any differences are insignificant.

Applicants traverse this rejection and withdrawal thereof is respectfully requested.

The extracts of EP '601 and U.S. '239 are the same as the extract disclosed in U.S. '760. Thus, the present invention is distinct from EP '601 and U.S. '239 for the reasons discussed above regarding U.S. '760. Withdrawal of the rejection is therefore respectfully requested.

Rejections under 35 U.S.C. §103

Claims 1-13 have been rejected under 35 U.S.C. §103 as being obvious over U.S. '627, U.S. '760, U.S. '780, EP '601 and U.S. '239. The Examiner asserts that it would have been obvious to administer the extract composition of the references to treat a tumor, viral infection and/or bacterial infection and that particular delivery systems are conventional and routine optimization. Applicants traverse this rejection and withdrawal thereof is respectfully requested.

As discussed above, the present invention has been defined in part by the process used to produce the claimed extract and the γδT cell enhancing activity associated with the extract. The γδT cell enhancing activity associated with the extract is dependent on the method used to prepare the extract. In addition, the method used to prepare the extract results in a demonstrated difference in component ingredient of the resulting extract. The recited method

used to prepare the extract of the invention, which results in the component composition and the γδT cell enhancing activity associated with the extract are in no way disclosed or suggested by any of the above-cited references. As such, the present invention is not obvious over the references and withdrawal of the rejection is respectfully requested.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact MaryAnne Armstrong (Reg. No. 40,069) at the telephone number below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

Attached hereto is a marked-up version of the changes made to the application by this Amendment.

Applicants respectfully request a three (3) month extension of time for filing the present response. The required fee is attached hereto.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,

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0230-0162P

Attachment: Version with Markings to Show Changes Made

(Rev. 02/20/02)

VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS:

Claims 1-13 have been canceled.

Claims 14-34 have been added.